

Notice of Allowability

Application No.

09/202,464

Examiner

Phuong Huynh

Applicant(s)

KINO ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/22/05.
2. ☒ The allowed claim(s) is/are 1,5,29-35 and 38-46.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>9/20/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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EXAMINER'S AMENDMENT

1. A supplemental examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Stuart Macphail on September 20, 2005.
3. **In the claims:**
The following listing of claims will replace all prior versions of listings of claims.

1. (Currently amended) A peptide derived from Japanese cypress pollen allergen Cha o 1, wherein the peptide consists of:

(i) (a) an amino acid sequence selected from the group consisting of SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO: 24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:29, SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36, said amino acid sequence having T-cell stimulating activity; or (b) a fragment of the amino acid sequence of (i)(a), the fragment being selected from fragments of the amino acid sequences listed in (i)(a), wherein each of the fragments has T-cell stimulating activity equivalent to that of the corresponding amino acid sequence of (i)(a); or

(ii) a combination of sequences, the sequences being selected from the amino acid sequences listed in (i)(a) and the amino acid sequence fragments recited in (i)(b).

2. - 4. (Cancelled)

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5. (Previously presented) A composition comprising the peptide of claim 1, as an active ingredient, and a pharmaceutically acceptable diluent or carrier.

6. - 28. (Cancelled)

29. (Currently amended) The peptide of claim 1, wherein the peptide consists of:

(A) an amino acid sequence selected from sequences of the group consisting of SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:29, SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36; or

(B) a combination of amino acid sequences selected from the sequences listed in (A).

30. (Currently amended) The peptide of claim 1, wherein the peptide consists of:

(x) an amino acid sequence selected from sequences of the group consisting of SEQ ID NO:4, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36; or

(y) a combination of amino acid sequences selected from the sequences listed in (x).

31. (Currently amended) The peptide of claim 1, wherein the peptide consists of:

(X) an amino acid sequence selected from sequences of the group consisting of SEQ ID NO:9, SEQ ID NO:24, SEQ ID NO:34, and SEQ ID NO:35; or

(Y) a combination of amino acid sequences selected from the sequences listed in (X).

32. (Previously presented) The composition of claim 5, wherein said composition can reduce the symptoms of Japanese cypress pollinosis or cedar pollinosis in a patient.

33. (Previously presented) A composition comprising the peptide of claim 29 as an active ingredient, and a pharmaceutically acceptable diluent or carrier.

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34. (Previously presented) A composition comprising the peptide of claim 30 as an active ingredient, and a pharmaceutically acceptable diluent or carrier.

35. (Previously presented) A composition comprising the peptide of claim 31 as an active ingredient, and a pharmaceutically acceptable diluent or carrier.

36. - 37. (Cancelled)

38. (Previously presented) The peptide of claim 39, wherein said linker is Arg-Arg or Lys-Lys.

39. (Currently amended) A peptide derived from Japanese cypress pollen allergen Cha o 1, wherein the peptide consists of a combination of two or more amino acid sequences and a linker sensitive to enzyme cleavage between each amino acid sequence, wherein said two or more amino acid sequences of the combination are:

sequences selected from the group consisting of SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:18, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO: 24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, SEQ ID NO:29, SEQ ID NO:32, SEQ ID NO:33, SEQ ID NO:34, SEQ ID NO:35, and SEQ ID NO:36, the sequences having T-cell stimulating activity; or

fragments of the sequences, each fragment having T-cell stimulating activity equivalent to that of the corresponding sequence.

40. (Previously presented) A composition comprising the peptide of claim 39, as an active ingredient, and a pharmaceutically acceptable diluent or carrier.

41. (Previously presented) A method for treating pollinosis caused by tree pollen in springtime, the method comprising administering the peptide of claim 1 to a patient that has pollinosis in the pollen-scattering season.

42. (Previously presented) A method for treating pollinosis caused by tree pollen in springtime, the method comprising administering the peptide of claim 39 to a patient that has pollinosis in the pollen-scattering season.

43. (Previously presented) A method of diagnosing pollinosis, the method comprising:

- (a) providing a population of cells from an individual, the population of cells comprising lymphocytes;
- (b) contacting said population of cells with a peptide of claim 1; and
- (c) detecting stimulation of the lymphocytes in response to the peptide as an indication that the individual is susceptible to pollinosis caused by Japanese cypress pollen allergens or by tree pollen allergens that are immunologically cross-reactive with Japanese cypress pollen allergens.

44. (Previously presented) A method of diagnosing pollinosis, the method comprising:

- (a) providing a population of cells from an individual, the population of cells comprising lymphocytes;
- (b) contacting said population of cells with a peptide of claim 39; and
- (c) detecting stimulation of the lymphocytes in response to the peptide as an indication that the individual is susceptible to pollinosis caused by Japanese cypress pollen allergens or by tree pollen allergens that are immunologically cross-reactive with Japanese cypress pollen allergens.

45. (Previously presented) An analog peptide consisting of a sequence identical to that of a wild-type peptide, except for substitution of one amino acid residue that mediate an interaction with a T cell receptor or that mediate an interaction with a major histocompatibility complex (MHC) class II molecule,

wherein the analog peptide has T-cell stimulating activity at least equivalent to that of the wild-type peptide, and

wherein the analog peptide consists of the amino acid sequence of SEQ ID NO: 89 or SEQ ID NO: 90.

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46. (Previously presented) The analog peptide of claim 45, wherein the analog peptide stimulates the T cell to produce an amount of interferon- γ greater than that stimulated by the wild-type peptide.

47. (Cancelled)

4. Claims 1, 5, 29-35, and 38-46 are pending and are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
6. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner

Technology Center 1600

September 26, 2005


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